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THOMAS Q. HENRY
WOODARD EMHARDT NAUGHTON & MCNETT
111 MONUMENT CIRCLE
SUITE 3700
INDIANAPOLIS, IN 46204

EXAMINER	
HART, K	
ART UNIT	PAPER NUMBER
3733	6

DATE MAILED: 07/01/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

See the attachment

Office Action Summary

Application No.

08/194548

Applicant(s)

Yimin, et al

Examiner

K. Hart

Group Art Unit

3733

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 (three) MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 19-36 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 19-22, 24-34 and 35-36 is/are rejected.
- ☒ Claim(s) 23 and 35 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: page 6, line 13. The example of "6,00 " does not fall within the disclosed range.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2173.05(l). The omitted structural cooperative relationships are: how the layers of the wound dressing are combined to form the wound dressing.
4. The term "hydroactive adhesive" in claim 35 is a relative term which renders the claim indefinite. The term "hydroactive adhesive" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 19-22, 24-34 and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Ewall (4,977,892).

7. In regard to Claim 19, note the adhesive layer of the wound dressing and its positive effects on the healing of the wound, col. 3, lines 17-19 and col. 8, lines 53-55, the hydrophilic second layer col. 3, lines 26-28 and a breathable film having an increased MVTR, col. 3, lines 38-39 and col. 9, lines 59-63. Note that the adhesive layer and fabric layer can be combined to make a single layer, col. 13, line 54, making the adhesive/fabric layer the wound contact layer.

8. In regard to Claims 20 and 21, note the characteristic of the adhesive layer to permit the passage of liquid, col. 3, lines 17-19 and the ability of the hydrophilic layer to absorb 2 to 20 times its weight in exudate, col. 3, line 45. It is inherent to the examiner that since the adhesive layer characteristically allows for the passage of exudate, only a negligible amount of exudate, if any, will remain in that layer. Since the second layer is hydrophilic, the exudate will be totally

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comprised in this layer. This denotes the hydrophilicity being drastically more than only twice that of the first layer.

9. In regard to Claim 22, note the response to Claims 20 and 21. Additionally, since a primary characteristic of the adhesive layer is to allow for the passage of liquid to an extent greater than that claimed, it is inherent to the examiner and would be obvious to one skilled in the art to have a wound contact layer within the range of that claimed since the thicker the layer, the more absorbency will occur and the higher the hydrophilicity of the second layer will have to be to absorb the liquid from the first layer.

10. In regard to Claims 24 and 25, it is inherent to the examiner and obvious to one of ordinary skill in the art to use a dressing, such as that claimed, for the purposes of debriding a wound and delivering components to a wound, since this is a common practice and purpose of wound dressings.

11. In regard to Claim 26, note the combined adhesive-fabric layer containing calcium alginate, col. 13, line 59.

12. In regard to Claim 27, it is inherent to the examiner and obvious to one of ordinary skill in the art to use a woven, non-woven or knitted fibrous material as an absorbent layer in a wound dressing, e.g. cotton, gauze, as such is a common practice in wound dressing manufacture.

13. In regard to Claim 28, it is inherent to the examiner and obvious to one of ordinary skill in the art to have a second more hydrophilic layer thicker than the first wound contact layer. The

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thicker the layer the greater the absorbency. An absorbance layer between 1-5 mm is a common thickness for an absorbent layer of dressing.

14. In regard to Claim 29, note the alginate or sodium carboxymethyl cellulose embodiment of the hydrophilic layer, col. 5, lines 44-46.

15. In regard to Claims 30 and 31, note that a major purpose of the wound dressing is to transmit moisture through the dressing, col. 9, lines 53-54, and that the MVTR for the film is specified, col. 9, lines 43-47. It is inherent to the examiner and obvious to one of ordinary skill in the art that increasing the MVTR of the film will increase the possibility of achieving the desired result of moisture or liquid migration. For one to increase the MVTR of a wound dressing to achieve this result would inherently be a common practice.

16. In regard to Claim 32, note the thickness of the cover layer, col. 9, line 50. The claimed film is thinner as would be expected if one were trying to increase the MVTR. It is inherent to the examiner and obvious to one of ordinary skill in the art that a thinner film would result in an increased MVTR. For one to decrease the film of a wound dressing to achieve this result would inherently be a common practice.

17. In regard to Claim 33, note the polyurethane film, col. 14, line 68.

18. In regard to Claim 34, note the purpose of the adhesive, col. 3, lines 18-20.

19. In regard to Claim 36, note the purpose of the dressing, col. 9, lines 53-60. It is inherent to the examiner and obvious to one of ordinary skill in the art that if the goal is to increase the

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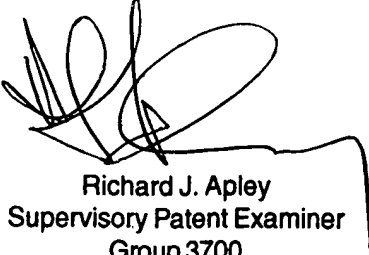
MVTR, that the thickness of the layer plays a very important and crucial role. As the thickness of the layer is decreased, the MVTR will increase. Since a major purpose for the wound dressing is to allow for the passage of moisture through the dressing, one decreasing the thickness of the adhesive layer to achieve an increased MVTR is inherently a common practice.

20. Claims 23 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kelvin Hart whose telephone number is (703) 306-4543.

keh

June 29, 1998



Richard J. Apley
Supervisory Patent Examiner
Group 3700